K101297
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## 510(k) Summary

JUN - 3 2010

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|---|---|
| **510(K) Owner's Name:** | Coloplast A/S |
| **Address:** | Holtedam 1<br>3050 Humlebaek, Denmark<br>Establishment Registration: 9610694<br>Owner/Operator: 8010144 |
| **Name of Contact Person:** | Angela Byland<br>Senior Regulatory Affairs Manager |
| **Phone and Fax Numbers:** | Phone: (612) 287-4236<br>Fax: (612) 287-4138<br>Email: usaby@coloplast.com |
| **Submission Date:** | May 7, 2010 |
| **Trade Name:** | Virtue™ Ventral Urethral Elevation Sling System |
| **Common or Usual Name:** | Sub-Urethral Sling System; Surgical Mesh |
| **Classification Name:** | Surgical Mesh, polymeric |

**Legally Marketed Device to Which Your Firm is Claiming Equivalence:**

The modified Coloplast Virtue Ventral Urethral Elevation Sling System is substantially equivalent in performance, indications, design and materials to the currently marketed Virtue Ventral Urethral Elevation Sling System, which was cleared under K082640 and K091152.

**Description of the Device:**

The modified Coloplast Virtue Ventral Urethral Elevation Sling System consists of a polypropylene mesh with four arms. The four arms are each covered with a sleeve and a suture is affixed at each end to allow for attachment to the introducer. The introducer consists of a handle and stainless steel wireform. The device kit (implant plus introducer) is provided sterile and for single use only.

**Intended Use Of The Device:**

The Coloplast Virtue Ventral Urethral Elevation Sling System is an implantable, suburethral support sling indicated for the treatment of male stress urinary incontinence (SUI).

**Technological Characteristics Compared To Predicate Device:**

Coloplast believes the proposed Coloplast Virtue Ventral Urethral Elevation Sling System is substantially equivalent in form and function to Coloplast's VIRTUE Ventral Urethral Elevation Sling System, which was cleared under 510(k) K082640 and K091152.

**Summary and Conclusions of the Nonclinical Tests Submitted:**

Substantial equivalency is supported by bench testing compared to the predicate device and existing specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Coloplast A/S
% Coloplast Corporation
Ms. Angela Byland
Senior Regulatory Affairs Manager
1601 West River Road North
MINNEAPOLIS MN 55411

OCT 12 2012

Re: K101297
Trade/Device Name: VIRTUE Ventral Urethral Elevation Sling System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTM
Dated: May 7, 2010
Received: May 10, 2010

Dear Ms. Byland:

This letter corrects our substantially equivalent letter of June 3, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

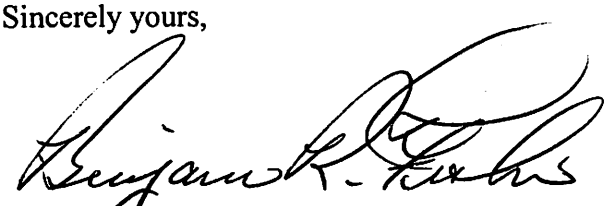
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K101297

Device Name: VIRTUE Ventral Urethral Elevation Sling System

Indications for Use:

The Coloplast VIRTUE Ventral Urethral Elevation Sling System is an implantable, suburethral support sling indicated for the treatment of male stress urinary incontinence (SUI).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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*(Posted November 13, 2003)* 510(k) Number K101297